DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 28, 2014

Handpiece Club, Limited Liability Company
C/O Dr. Tina Wu
Regulatory Project Manager
Aptiv Solutions
62 Forest Street, Suite 300
Marlborough, MA 01752

Re: K142063
Trade/Device Name: #8c Renegade Dental Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: July 29, 2014
Received: July 30, 2014

Dear Dr. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,


Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 4. INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Indications for Use**

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)* K142063

Device Name
#8C Renegade Dental Handpiece

Indications for Use *(Describe)*
The #8C Renegade Dental Handpiece is intended for use in general dentistry by licensed professionals for removing carious material, reducing hard tooth surfaces, cavity preparation, finishing tooth preparations, restorations and polishing teeth.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**FORM FDA 3881 (1/14)** Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

# 510(k) Summary for the Handpiece Club, LLC
# #8C Renegade Dental Handpiece

**(per 21CFR 807.92 and *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm*)**

## 1. SUBMITTER/510(K) HOLDER

Handpiece Club, LLC
6960 Westcliff Drive
Las Vegas, NV 89145

Contact Person: Chen-Yu Chen, CEO
Telephone: 702-541-9874

Date Prepared: July 29, 2013

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | #8C Renegade Dental Handpiece |
| Common/Usual Name: | Handpiece, dental, high speed, air turbine |
| Classification Name: | 21 CFR 872.4200 Dental handpieces and accessories |
| Class: | I |
| Classification Panel: | Dental |
| Product Code: | EFB |

## 3. PREDICATE DEVICES

- Thunder Tiger Dental Air-Powered Handpiece (K052822)

## 4. DEVICE DESCRIPTION

The #8C Renegade is a high speed air turbine handpiece with a push-button autochuck. The handpiece is powered by compressed air (26-35 psi) which activates an air turbine causing rotation of the chuck holding a burr (not supplied with the handpiece) at 380,000-530,000 rpm. The handpiece handle and head are constructed of chrome plated brass. The handpiece features a four (4) hole connector for air and water input and return. The head and burr are cooled by a water/air mist.

The handpiece is supplied non-sterile and must be cleaned, lubricated and sterilized prior to each patient use.

## 5. INDICATION FOR USE/INTENDED USE

The #8C Renegade Dental Handpiece is intended for use in general dentistry by licensed professionals for removing carious material, reducing hard tooth surfaces, cavity preparation, finishing tooth preparations, restorations and polishing teeth.

## 6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

The #8C Renegade Dental Handpiece is substantially equivalent to the Thunder Tiger Dental Air-Powered Handpiece (K052822) in terms of the indications for use, design (e.g., dimensions, type of chuck, type of connector), principles of operation, and technological characteristics. Both the proposed and predicate device are provided non-sterile and can be reused. The product must be cleaned and sterilized prior to each patient use.

## 7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Bench testing demonstrates that the #8C Renegade Dental Handpiece is substantially equivalent to the predicate device and is as safe and effective as the predicate device for the intended use described above. Additionally, the finished, sterilized device meets ISO 10993-1 biocompatibility requirements.

## 8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted to support this submission.

## 9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the descriptive information and performance testing, Handpiece Club, LLC has determined that the proposed #8C Renegade Dental handpiece is substantially equivalent to the predicate the Thunder Tiger Dental Air-Powered Handpiece (K052822) based on the similarities in intended use operational characteristic and functional characteristics. Differences between the two devices are minor and do not raise new safety or effectiveness issues. A side-by-side comparison of the predicate device and the proposed device is provided in the table at the end of this section.

## Table 5-1. Side-by-Side Comparison of the #8C Renegade Dental Handpiece with Predicate Device

| Device Name | #8C Renegade Dental Handpiece (Handpiece Club, LLC) | Dental Air Powered Handpiece (Thunder Tiger Corp.) |
|---|---|---|
| **Regulatory Status** | Proposed device | K052822 |
| **Indications for Use** | The #8C Renegade Dental Handpiece is intended for use in general dentistry by licensed professionals for removing carious material, reducing hard tooth surfaces, cavity preparation, finishing tooth preparations, restorations and polishing teeth. | Thunder Tiger Dental Air-Powered Handpiece, models Tiger 100, Tiger 101, Tiger 200, Tiger 201, Tiger 202 are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth. |
| **Device Design** | | |
| **Operational Mode** | 4-holes | 4-holes (feature on models #101-T4/M4 and #101-3T4/3M4) |
| **Fiber Optics** | No | No |
| **Dimensions** | Head: Φ12.5mm X 13.3mm<br>Length: 123.1mm | Head: Φ12mm X 12mm to Φ 12mm X 12.4mm<br>Length: not provided by the manufacturer |
| **Type of chuck** | Push-button autochuck | Push-button autochuck |
| **Type of connector** | ISO-B, Midwest coupler | ISO-B, Midwest coupler |
| **Materials** | Waterline: 440C stainless steel<br>Surface: chrome plated brass | Surface: Chrome plated |
| **Specifications** | | |
| **Burr Extraction Force** | 26 N | 35 N |
| **Burr Size** | 1.6 diameter<br>19mm length | 1.59-1.60 diameter<br>19-25mm and 16-21mm length |
| **Water flow rate** | 120mL/min | >50mL/min |
| **Air pressure** | 2.0bar | 1.0-3.0bar |
| **Speed (rpm)** | 380,000-530,000 | ≥ 300,000 |
| **Lubricant** | Lubricant is required | Lubricant is required |
| **Sterility** | Provided non-sterile, must be cleaned and sterilized prior to each patient use | Provided non-sterile, must be sterilized prior to each patient use |